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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/785,106 | 02/25/2004 | Ming-Hui Wei | CL001180DIV | 1623 |

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CELERA GENOMICS
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| EXAMINER | |
|---|---|
| VANDERVEGT, FRANCOIS P | |
| **ART UNIT** | **PAPER NUMBER** |
| 1644 | |

DATE MAILED: 07/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/785,106 | WEI ET AL. | |
| | Examiner | Art Unit | |
| | F. Pierre VanderVegt | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *18 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-3 and 24-38* is/are pending in the application.

4a) Of the above claim(s) *1,2,37 and 38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3 and 24-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20050506*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

This application is a divisional of U.S. Application Serial Number 09/815,048.

Claims 4-23 have been canceled.

New claims 24-38 have been added.

### *Election/Restrictions*

1. Applicant's election with traverse of Group II, claim 3, in the reply filed on May 18, 2006 is acknowledged. The traversal is on the ground(s) that the additional search of Group I would not constitute a serious burden on the Examiner because a search of the peptide of Group I is inherent in the search of the antibody of Group II. This is not found persuasive because the polypeptide of Group I can be obtained independently of the antibody of Group II.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-2 and newly added claims 37-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on May 18, 2006.

Accordingly, claims 3 and 24-36 are the subject of examination in the present Office Action.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 3 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker et al (Biochem. Biophys. Res. Comm. [1995] 213(1):154-160; U on form PTO-892) in view of Campbell (Monoclonal Antibody Technology [1985] pages 1-32; V on form PTO-892).

Baker teaches the isolation and sequence of lanasterol synthase (see entire document, Figure 2 in particular). With respect to claim 3, the lanasterol synthase taught by Baker differs from instant SEQ ID NO: 2 only by the deletion of an 11 amino acid residue segment in the instantly disclosed SEQ ID NO: 2 versus the longer polypeptide taught by Baker, as evidenced by Figure 2c of the instant specification.

Baker does not teach making monoclonal antibodies to lanasterol synthase. With respect to claim 24, a sequence comprising SEQ ID NO: 2 encompasses the lanasterol synthase taught by Baker.

Campbell teaches that "[i]t is customary now for any group working on a macromolecule to both clone the genes coding for it and make monoclonal antibodies to it (sometimes without a clear objective for their application)" (page 29, section "Basic research" in particular). It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to make antibodies specific lanasterol synthase comprising the sequence of SEQ ID NO: 2. One would have been motivated, with a reasonable expectation of success, to generate mAbs to the peptides based on the fact that it is a conventional practice in the art to do so for further study, characterization and identification of a specific peptide and because of the role of lanasterol synthase in the biosynthesis of steroids as taught by Baker. While the lanasterol synthase protein taught by Baker is slightly longer than the instantly disclosed SEQ ID NO: 2, the artisan would reasonably expect that antibodies would be generated to epitopes distributed over the full length of lanasterol synthase and not just to the 11-amino acid segment of lanasterol synthase that is missing from SEQ ID NO: 2. There are no regions of instant SEQ ID NO: 2 that are not present in the lanasterol synthase protein taught by Baker.

4. Claims 3 and 24-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker et al (Biochem. Biophys. Res. Comm. [1995] 213(1):154-160; U on form PTO-892) in view of Campbell (Monoclonal Antibody Technology [1985] pages 1-32; V on form PTO-892) and Harlow et al. (Antibodies: A Laboratory Manual. [1988] pages 72-77, 92-97, 128-135, 141-157 and 628-631; W on form PTO-892).

Baker and Campbell have been discussed supra.

The combined references do not teach antibody fragments.

Harlow teaches that any substance which can elicit a humoral response can be used to prepare mAbs and that mAbs are powerful reagents for the testing for the presence of a desired epitope. Harlow

teaches methods for immunizing animals for the production of polyclonal and monoclonal antibodies (pages 72-77, 92-97, 128-135 and 141-157 in particular) as well as the types of antigens to which such antibodies can be made including proteins, peptides, and carbohydrates (any of which could qualify as a ligand, depending on the receptor)(pages 153-154 in particular). Harlow further teaches that because antibodies may recognize small determinants they may be cross-reactive with similar epitopes on other molecules (page 24, last paragraph in particular) and that epitopes may be formed by linear epitopes within an amino acid sequence or to epitopes which are formed by determinants from different parts of a molecule which are brought together due to conformation of said molecule (page 25, first section in particular). Harlow further teaches the manufacture of Fab and $F(ab')_2$ fragments of monoclonal antibodies (pages 628-631 in particular). harlow also teaches the conventional practice of labeling antibodies (pages 321-323 in particular).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine these references to produce monoclonal antibodies to the NTPPH protein taught by Cardenal. One would have been motivated, with a reasonable expectation of success, to combine these references in order to generate monoclonal antibodies to NTPPH to assist in the identification of regions of the protein involved in the enzyme activity of NTPPH by Harlow's teaching that hybridomas which produce mAbs provide a limitless supply of antibodies which is desirable because even large supplies of antisera (polyclonal) will eventually run out (pages 141-142, section titled "Monoclonal antibodies are powerful immunochemical tools").

Claims 31-34 are included because any conventional diluent, such as water, physiological saline or PBS, would constitute such a "carrier" irrespective of the intended use.

*Conclusion*

5. No claim is allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

F. Pierre VanderVegt, Ph.D.
Patent Examiner
June 26, 2006

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182 1644